UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

x

UNITED STATES OF AMERICA *ex rel.* DAVID M. KESTER, STATE OF CALIFORNIA *ex rel.* DAVID M. KESTER, STATE OF COLORADO *ex rel.* DAVID M. KESTER, STATE OF CONNECTICUT *ex rel.* DAVID M. KESTER, STATE OF DELAWARE *ex rel.* DAVID M. KESTER, DISTRICT OF COLUMBIA *ex rel.* DAVID M. KESTER, STATE OF FLORIDA *ex rel.* DAVID M. KESTER, STATE OF GEORGIA *ex rel.* DAVID M. KESTER, STATE OF HAWAII *ex rel.* DAVID M. KESTER, STATE OF ILLINOIS *ex rel.* DAVID M. KESTER, STATE OF INDIANA *ex rel.* DAVID M. KESTER, STATE OF LOUISIANA *ex rel.* DAVID M. KESTER, STATE OF MARYLAND *ex rel.* DAVID M. KESTER, STATE OF MASSACHUSETTS *ex rel.* DAVID M. KESTER, STATE OF MICHIGAN *ex rel.* DAVID M. KESTER, STATE OF MINNESOTA *ex rel.* DAVID M. KESTER, STATE OF MONTANA *ex rel.* DAVID M. KESTER, STATE OF NEVADA *ex rel.* DAVID M. KESTER, STATE OF'NEW JERSEY *ex rel.* DAVID M. KESTER, STATE OF NEW MEXICO *ex rel.* DAVID M. KESTER, STATE OF NEW YORK *ex rel.* DAVID M. KESTER, STATE OF NORTH CAROLINA *ex rel.* DAVID M. KESTER, STATE OF OKLAHOMA *ex rel.* DAVID M. KESTER, STATE OF RHODE ISLAND *ex rel.* DAVID M. KESTER, STATE OF TENNESSEE *ex rel.* DAVID M. KESTER, STATE OF TEXAS *ex rel.* DAVID M. KESTER, STATE OF VIRGINIA *ex rel.* DAVID M. KESTER, and STATE OF WISCONSIN *ex rel.* DAVID M. KESTER,

Plaintiffs and Relator,

-against-

No. 11 Civ. 8196 (CM)

NOVARTIS PHARMACEUTICALS CORPORATION, ACCREDO HEALTH GROUP, INC., BIOSCRIP CORPORATION, CURASCRIPT, INC., CVS CAREMARK CORPORATION,

Defendants.

x

MEMORANDUM DECISION AND ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTIONS TO DISMISS

McMahon, J.:

Plaintiff-relator David M. Kester ("Relator") filed a sealed *qui tam* action asserting claims against Novartis Pharmaceuticals Corporation ("Novartis") and several pharmacies under the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, and related state laws. Eleven states (the "Intervening States") and the United States government (the "Government") subsequently chose to intervene as co-plaintiffs against Novartis alone. The Intervening States include California, Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, Washington, and Wisconsin. In three separate complaints, the Intervening States allege that Novartis violated the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and parallel state statutes, in connection with a kickback scheme. They bring claims against Novartis under their respective state false claims statutes and related state laws.

Pending before the Court are Defendant Novartis's motions to dismiss the three state complaints pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure. For the reasons discussed below, these motions are granted in part and denied in part.[1]

[1] This opinion is to be referred to in all future correspondence and papers as "*Novartis VI*."

BACKGROUND[2]

The reader is presumed to be familiar with the Court's previous orders in this case: denying Novartis's motion to dismiss the Government's Complaint pursuant to Rule 9(b), *see U.S. ex rel. Kester v. Novartis Pharm. Corp.*, No. 11 Civ. 8196 (CM), 2014 WL 2324465 (S.D.N.Y. May 29, 2014) ("*Novartis I*"); granting in part and denying in part Defendants' motions to dismiss the Relator's Second Amended Complaint pursuant to Rule 9(b), *see U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 11 Civ. 8196 (CM), 2014 WL 2619014 (S.D.N.Y. June 10, 2014) ("*Novartis II*"); denying Defendants' motion for reconsideration of this Court's order in *Novartis II* ("*Novartis III*"), *see* Docket No. 216; granting in part and denying in part Novartis's motion to dismiss the Government's Complaint pursuant to Rules 12(b)(6) and 9(b), *see U.S. ex rel. Kester v. Novartis Pharm. Corp.*, 11 Civ. 8196 (CM), 2014 WL 4230386 (S.D.N.Y. Aug. 7, 2014) ("*Novartis IV*"); and granting in part and denying in part Defendants' motions to dismiss the Relator's Complaint pursuant to Rules 12(b)(1), 12(b)(6), and 9(b) ("*Novartis V*"), *see* Docket No. 233.

Generally, the FCA outlaws the submission of a false "claim" for payment (*i.e.*, a request for reimbursement) to the government. *See* 31 U.S.C. § 3729(a)(1). Each of the Intervening States has a state statute that is parallel to the FCA. The Intervening States bring causes of action under their respective state false claims statutes.[3]

---

[2] The facts are taken from the three state complaints-in-intervention. Nine of the Intervening States (Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, and Wisconsin) filed a joint complaint-in-intervention (the "Multistate Complaint"). The States of California and Washington each filed separate complaints (the "California Complaint" and the "Washington Complaint"). The contents of the three complaints are substantially the same. Indeed, the Washington Complaint expressly incorporates the allegations of the Multistate Complaint. *See* Washington Compl. at ¶ 56. I will refer to the three complaints collectively as the "State Complaints."

[3] The State of Washington is the only state that does not assert state FCA claims.

Under the FCA and its state law parallels, claims may be rendered "false" in a variety of ways. In this case, the Intervening States' claims are predicated on underlying violations of the Anti-Kickback Statute ("AKS") and its state law parallels. The AKS makes it illegal to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person" to "purchase or . . . recommend purchasing" a drug that is covered by a "Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Likewise, the AKS proscribes "knowingly and willfully solicit[ing] or receiv[ing] any remuneration (including any kickback, bribe, or rebate)" "in return for purchasing . . . or recommending purchasing" a drug covered by a "Federal health care program." *Id.* § 1320a-7b(b)(1). State Medicaid programs qualify as "Federal health care program[s]," since they are partially funded by the federal government. *Id.* § 1320a-7b(f). Thus, the AKS forbids offering, paying, soliciting, or receiving "remuneration" (*i.e.*, kickbacks) in exchange for recommending drugs covered by Medicaid.

In three separate complaints (the "State Complaints"), the Intervening States allege that Novartis conducted a kickback scheme involving drugs covered by state Medicaid programs.

A. The Alleged Kickback Scheme

Defendant Novartis is a pharmaceutical company that develops, manufactures, and markets prescription drugs. It sells these drugs through various avenues, one of which is pharmacies.

According to the Intervening States, Novartis realized that certain "specialty pharmacies" (including a pharmacy named BioScrip) had influence over patients. So it decided to offer BioScrip kickbacks in exchange for recommending to patients that they order refills for a drug named Exjade, in violation of the AKS and parallel state statutes.

Exjade is an iron chelation drug that is given to patients who receive blood transfusions in order to prevent iron overload in the blood. *See* Multistate Compl. at ¶ 57. Novartis coordinates the dispensing of Exjade through its exclusive distribution network—Exjade Patient Assistance & Support Services ("EPASS"). Through EPASS, Novartis controls which specialty pharmacies receive patient referrals for new Exjade prescriptions. *See id.* at ¶ 72. The pharmacies dispense Exjade to patients, contact them about refills, and provide patient "counseling." *Id.* at ¶ 3.

BioScrip has been a member of the EPASS network since 2005. *See id.* at ¶ 68. In February 2007, Novartis allegedly placed BioScrip under a "performance improvement plan;" it imposed new conditions on BioScrip's continued access to the EPASS network and its ability to earn rebates, which were $13 per Exjade shipment. *Id.* at ¶¶ 71, 81. Under this plan, Novartis required BioScrip to commit to increasing the refill rates among its Exjade patients, and to convincing patients who had stopped ordering refills to resume doing so. BioScrip complied with Novartis's demands. *See id.* at ¶¶ 82-84. Its pharmacy staff called patients to offer purported "counseling" about Exjade therapy. The Intervening States allege that these calls were actually designed to get patients to order refills, and that Novartis's marketing team was directly involved in formulating BioScrip's "counseling" strategy. *See id.* at ¶¶ 84-90.

By late 2007, Novartis recognized that BioScrip had become very effective in generating refills. Novartis's internal studies stated that "an Exjade patient [at] BioScrip is worth $800-$2,800 more than a patient serviced by another [pharmacy]." *Id.* ¶ 91. To ensure that BioScrip would continue promoting Exjade refills to patients, Novartis gave the pharmacy benefits including more patient referrals and higher rebates on each sale (*i.e.*, kickbacks). *See id.* at ¶¶ 92-93. In exchange, BioScrip committed to "mirror and support Novartis priorities," and it

continued to recommend Exjade refills to patients. *Id.* at ¶ 99. The Intervening States allege that the Exjade "refill" scheme lasted from February 2007 to May 2012.

Based on these facts, the State Complaints allege that Novartis and BioScrip violated the AKS in connection with their dealings in Exjade; Novartis paid "remuneration" to BioScrip to induce the pharmacy to "recommend" Exjade to patients. 42 U.S.C. § 1320a-7b(b)(2). The Intervening States allege that Novartis paid the pharmacies two types of "remuneration" (*i.e.*, kickbacks) during the course of the scheme: (1) cash "rebates" for each sale of Exjade, and (2) patient referrals through EPASS, in exchange for BioScrip's efforts to promote Exjade. Multistate Compl. at ¶ 71. They argue that these AKS violations rendered "false" all the claims for Exjade that BioScrip submitted to state Medicaid programs during the course of the scheme.

B. The State Complaints

The Intervening States assert 69 causes of action against Novartis in the three State Complaints.

Nine of the Intervening States (Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, New York, Oklahoma, and Wisconsin) filed a joint complaint-in-intervention (the "Multistate Complaint") that asserts 56 claims against Novartis. *See* Docket No. 61. In the Multistate Complaint, each of the states brings claims under its respective state FCA provisions that are parallel to FCA subsection (a)(1)(A) (presentation of a false claim), subsection (a)(1)(B) (making a false statement material to a false claim), and subsection (a)(1)(C) (conspiracy to submit false claims), 31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B), (a)(1)(C). The Multistate Complaint alleges that Novartis caused BioScrip to both present false claims to state Medicaid programs and to make false statements material to false claims. It further alleges that Novartis engaged in

a conspiracy with BioScrip to submit false claims. The state FCA claims are included in Counts 1-3, 5-8, 11-13, 17-20, 25-28, 31-33, 38-40, 46-48, and 53-55.

In the Multistate Complaint, each state brings other statutory and common law causes of action. Every state brings a claim for unjust enrichment (Counts 4, 10, 16, 24, 30, 37, 44, 52, and 56). In addition, the State of Illinois asserts a statutory claim for public assistance fraud (Count 9). The State of Indiana asserts a statutory claim for Medicaid fraud (Count 14) and a common law claim for theft (Count 15). The State of Maryland asserts common law claims for intentional misrepresentation (Count 21), negligent misrepresentation (Count 22), and constructive fraud (Count 23). The State of Michigan asserts a claim for common law fraud (Count 29). The State of New Jersey asserts a statutory claim for Medicaid false statement (Count 34) and common law claims for conversion (Count 35) and fraud (Count 36). The State of New York asserts statutory claims for repeated fraudulent acts (Count 42), misappropriation of public property (Count 43), and "false statement," in violation of the New York Social Services Law (Count 41). The State of Oklahoma asserts two statutory claims under the state Medicaid Program Integrity Act for "kickbacks" (Count 45) and a Medicaid program integrity violation (Count 49); it also brings common law claims for fraud (Count 50) and civil conspiracy (Count 51).

The State of California filed a separate amended complaint-in-intervention (the "California Complaint") that asserts five claims against Novartis. *See* Docket No. 162. Like the Multistate Complaint, it asserts claims under the statutory provisions in its state false claims act that are parallel to FCA subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C) (Counts 1-4).[4] The California Complaint also brings a claim for unjust enrichment (Count 5).

[4] The California Complaint designates two of its claims as "Count 3." For clarity, I will refer to the second "Count 3" as "Count 4," and I will refer to the claim designated "Count 4" as "Count 5."

Finally, the State of Washington filed a complaint-in-intervention (the "Washington Complaint") that asserts eight claims against Novartis. *See* Docket No. 82. In Counts 1-3, it asserts statutory claims for fraudulent practices under the Washington Medicaid statute for "obtain[ing] or attempt[ing] to obtain benefits or payments under this chapter in a greater amount than that to which entitled by means of: (a) A willful false statement; (b) By willful misrepresentation, or by concealment of any material facts; or (c) By other fraudulent scheme or device . . ." RCW 74.09.210(1)(a)-(c). The Washington Complaint also asserts common law claims for fraud (Count 4), unjust enrichment (Count 5), money had and received (Count 6), tortious interference with business expectation (Count 7), and civil conspiracy (Count 8). It does not bring claims under Washington's state false claims statute.

Novartis has moved to dismiss all claims in the three State Complaints pursuant to Rule 12(b)(6) for failure to state a claim and pursuant to Rule 9(b) for failure to plead fraud with particularity.

DISCUSSION

I. Standard of Review

In deciding a motion to dismiss pursuant to Rule 12(b)(6), the Court must liberally construe all claims, accept all factual allegations in the complaint as true, and draw all reasonable inferences in favor of the plaintiff. *See Cargo Partner AG v. Albatrans, Inc.*, 352 F.3d 41, 44 (2d Cir. 2003); *see also Roth v. Jennings*, 489 F.3d 499, 510 (2d Cir. 2007).

However, to survive a motion to dismiss, "a complaint must contain sufficient factual matter . . . to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the

reasonable inference that the defendant is liable for the misconduct alleged." *Id.* (citing *Twombly*, 550 U.S. at 556). "While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555 (internal quotations, citations, and alterations omitted). Thus, unless a plaintiff's well-pleaded allegations have "nudged [its] claims across the line from conceivable to plausible, [the plaintiff's] complaint must be dismissed." *Id.* at 570; *see also Iqbal*, 556 U.S. at 680.

This liberal pleading standard is modified by Rule 9(b), which requires a plaintiff asserting fraud claims to meet a heightened pleading standard. While Rule 8(a) usually requires only a "short and plain statement of the claim showing that the pleader is entitled to relief," FED. R. CIV. P. 8(a), a plaintiff asserting fraud must "state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). Rule 9(b) applies to state law fraud claims brought in federal court, including claims brought under state analogues of the FCA. *See U.S. ex rel. Polansky v. Pfizer, Inc.*, No. 04 Civ. 704, 2009 WL 1456582, at *4 (E.D.N.Y. May 22, 2009).

II. The State FCA Claims

A. The Intervening States Adequately Allege That BioScrip Submitted "False" Claims.

The Intervening States premise their causes of action under the state false claims statutes on the assertion that Novartis's kickback scheme led BioScrip to submit "false" claims to state Medicaid programs. Novartis argues that the Intervening States have not adequately pled that the claims at issue in this case were "false" within the meaning of the state FCA statutes;

accordingly, Novartis moves to dismiss those claims pursuant to Rule 12(b)(6) for failure to state a claim.

As discussed in *Novartis V*, the state law parallels to FCA subsections (a)(1)(A), (a)(1)(B), and (a)(1)(C), 31 U.S.C. §§ 3729(a)(1)(A)-(C)—which are the provisions that the Intervening States invoke—require a plaintiff to prove either the existence of "false" claims or a conspiracy involving "false" claims. *See* Docket No. 233 at 40-41.

In *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001), the Second Circuit established the definition of a "false" claim in this Circuit: it is any claim "aimed at extracting money the government otherwise would not have paid." *Id.* at 696. Under *Mikes*, a claim may be rendered legally "false" by either "express" or "implied" false certifications of compliance with a statute that is a precondition to payment of a claim. The requirements for such false certifications are discussed at length in *Novartis IV* and *Novartis V* and incorporated here by reference. *See Novartis IV*, 2014 WL 4230386 at *3-4; *Novartis V* at 41-43.

The Intervening States argue that BioScrip made "express" and "implied" certifications of compliance with the AKS and parallel state statutes in connection with the Exjade claims it submitted during the course of the kickback scheme. Because BioScrip was actually engaged in a kickback scheme with Novartis, the Intervening States contend, those compliance certifications and the corresponding claims were "false."

Novartis argues that false certifications of compliance are insufficient to render claims "false" where FCA claims are predicated on underlying AKS violations. For the reasons set forth in *Novartis IV*, this argument fails. *See* 2014 WL 4230386 at *3-10.

Novartis also challenges the adequacy of the "express" and "implied" certifications identified by the Intervening States.

1. The Intervening States Adequately Allege That BioScrip Made "Implied" False Certifications In Connection With Claims Submitted After March 2010.

In *Mikes*, the Second Circuit limited use of the "implied" false certification theory to instances "when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." 274 F.3d at 700 (emphasis in original). As discussed in *Novartis IV*, in 2010 the Patient Protection and Affordable Care Act ("PPACA") amended the AKS to make explicit that AKS compliance is a precondition to the payment of any claims submitted to federal health care programs. *See* 42 U.S.C. § 1320a-7b(g). Accordingly, from and after the effective date of the PPACA (March 23, 2010), "the act of submitting a claim for reimbursement itself implie[d] compliance with" the AKS. *Mikes*, 274 F.3d at 699.

Thus, when BioScrip submitted claims to state Medicaid programs after March 2010, it impliedly certified that it complied with the AKS in connection with the underlying sales of those drugs. The Intervening States allege that these implied certifications of AKS compliance were "false" for Exjade claims, given the existence of the kickback scheme. This adequately alleges that all the Exjade claims BioScrip submitted to state Medicaid programs after March 23, 2010 were "false."

However, the AKS did not "expressly" state that it was a precondition to payment of claims submitted to federal health care programs prior to March 2010; it thus does not provide a basis for implied certifications before that date under *Mikes*. *See id.* at 700. Accordingly, the Intervening States have failed to allege that BioScrip made implied false certifications with the AKS that rendered the claims it submitted prior to March 2010 "false." *See Mikes*, 274 F.3d at 700; *U.S. ex rel. Urbanek v. Lab. Corp. of Am. Holdings, Inc.*, No. 00 Civ. 4863, 2003 U.S. Dist. LEXIS 27469 at *23 (E.D. Pa. Aug. 14, 2003) (E.D. Pa. Nov. 21, 2003).

2. The Intervening States Adequately Allege That BioScrip Made "Express" False Certifications In Connection With Claims Submitted to Many of the State Medicaid Programs Prior to March 2010.

The Intervening States allege that their Medicaid programs required participating pharmacies (including BioScrip) to make express certifications of compliance with the AKS in their Medicaid enrollment agreements.

a. The California Complaint

The California Complaint alleges that "California requires providers, such as BioScrip, to certify or agree in the Medi-Cal Provider Agreement, that they will comply with all state and federal laws, such as the anti-kickback laws, that relate to the provision of goods and services under the Medi-Cal program." California Compl. at ¶ 25. The Medi-Cal Provider Agreement identified in the California Complaint includes a certification that states: "Provider agrees to comply with all applicable provisions of Chapters 7 and 8 of the Welfare and Institutions Code . . . . Provider further agrees to comply with all federal laws and regulations governing and regulating Medicaid providers." Medi-Cal Provider Agreement, Form DHCS 6208, at 1, http://www.denti-cal.ca.gov/provsrvcs/forms/dhcs6208_9106.pdf (last visited Sept. 4, 2014). "Chapters 7 and 8 of the Welfare and Institutions Code" contain California's anti-kickback statute, and the federal AKS is one of the "federal laws . . . governing and regulating Medicaid providers" referenced in the agreement. *Id.* Thus, California's provider agreement requires providers like BioScrip to expressly certify to their compliance with both the federal and state anti-kickback provisions.

California alleges that BioScrip's express compliance certifications were false with respect to the Exjade claims it submitted during the course of the kickback scheme because the pharmacy did not "comply with all federal laws . . . governing and regulating Medicaid

providers;" it received kickbacks from Novartis on those drug sales. California contends that BioScrip's false certifications rendered its Exjade claims ineligible for repayment and, thus, "false." These allegations suffice.

Accordingly, California has adequately alleged that the Exjade claims that BioScrip submitted to California Medicaid were rendered "false" by the pharmacy's false certifications for the entire time period at issue—February 2007 to May 2012.

b. The Multistate Complaint

The Multistate Complaint generally alleges: "As part of their Medicaid enrollment process, each of the Intervening States requires providers to certify or agree that they will comply with state and federal laws, such as anti-kickback laws, that relate to the provision of goods and services under the Medicaid program." Multistate Compl. ¶ 39. It provides one example enrollment agreement certification—New York Medicaid's "Certification Statement for Provider Billing Medicaid," which states: "I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so *in accordance with applicable federal and state laws* and regulations." *Id.* (emphasis added). This Court held in *Novartis IV* that this statement constitutes an adequate express certification of compliance with the AKS. *See* 2014 WL 4230386, at *14.

The Multistate Complaint asserts that the express certifications that BioScrip submitted to New York Medicaid were "false" insofar as they concerned Exjade claims, because BioScrip did not "furnish[] the . . . supplies itemized . . . in accordance with applicable federal and state laws," Multistate Compl. ¶ 39; rather, BioScrip accepted kickbacks from Novartis on those drug sales. Thus, the Intervening States have adequately pled that that the Exjade claims that BioScrip

submitted to New York Medicaid were rendered "false" by the pharmacy's false certifications for the entire time period at issue.

However, the Multistate Complaint does not mention any similar express certifications that BioScrip made in connection with the claims it submitted to the rest of the state Medicaid programs—Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, Oklahoma, and Wisconsin Medicaid. Instead, the Multistate Complaint makes a general allegation that the states required Medicaid providers to make such certifications; it offers no specific facts to support this assertion. Without more, this conclusory allegation is insufficient to plead that BioScrip made express false certifications of compliance in connection with claims submitted to those eight Medicaid programs prior to March 2010. *See Novartis IV*, 2014 WL 4230386, at *14.

Thus, the Multistate Complaint fails to plead any "express" or "implied" false certifications that rendered the claims submitted to the Medicaid programs for Georgia, Illinois, Indiana, Maryland, Michigan, New Jersey, Oklahoma, and Wisconsin "false" within the meaning of the state FCA statutes prior to March 2010. Accordingly, the state FCA claims for those states would ordinarily be dismissed (though without prejudice) insofar as they concern those claims for repayment.

In their brief in opposition to the motions to dismiss, the Intervening States point to "express" and "implied" certifications of AKS compliance that are nowhere mentioned in the Multistate Complaint. A plaintiff may not amend a pleading through an opposition brief. *See O'Brien v. Nat'l Prop. Analysts Partners*, 719 F. Supp. 222, 229 (S.D.N.Y. 1989). But I will construe the opposition brief's reference to these certifications as a request for leave to amend the Multistate Complaint to incorporate these certifications. I deem the Multistate Complaint amended to include the compliance certifications referenced in the Intervening States' brief for

the following state Medicaid programs: Georgia, Wisconsin, Oklahoma, Indiana, Maryland, and New Jersey.

The Intervening States' brief points to "express" compliance certifications for three states: Georgia, Wisconsin, and Oklahoma.[5]

First, the brief refers to a "Statement of Participation" required by Georgia Medicaid for its participating providers. Pl. Opp.[6] at 10 n.4. Under "Provider's Obligations," this certification states: "Provider shall comply with all of the Department's requirements applicable to the category(ies) of service in which Provider participates under this Statement of Participation, including Part I, Part II and the applicable Part III manuals." Georgia Department of Community Health, Division of Medical Assistance, Form DMA-002, at 2, http://dbhdd.georgia.gov/sites/dbhdd.georgia.gov/files/imported/DBHDD/Files/Medicaid%20Application%20Instructions.pdf (last visited Sept. 4, 2014).

"Part I" of the Georgia Medicaid Manual (which is referenced in the Statement of Participation) includes Section 106, which requires participating providers to "[c]omply with all State and Federal laws and regulations related to furnishing Medicaid/PeachCare for Kids services." Georgia Department of Community Health, Division of Medicaid, Part I: Policies and Procedures for Medicaid/PeachCare for Kids, § 106, https://advocacy.gha.org/Portals/1/Documents/Advocacy/Finance/PoliciesPCK.pdf (last visited Sept. 4, 2014). Section 106 also prohibits kickbacks: "Any offer or payment of remuneration, whether direct, indirect, overt,

[5] The Intervening States also repeat their conclusory assertion that Maryland Medicaid requires participating providers to make express certifications of compliance with the AKS, but they provide no facts supporting this assertion. Nor do they reference express certifications for the Illinois, Michigan, Indiana, or New Jersey Medicaid programs.

[6] "Pl. Opp." refers to the Intervening States' brief in opposition to the motion to dismiss the State Complaints.

covert, in cash or in kind, in return for the referral of a Medicaid or PeachCare for Kids member is also prohibited." *Id.*

A pharmacy's agreement to Georgia Medicaid's Statement of Participation constitutes an express certification of compliance with the AKS, given that the AKS is one of the "Federal laws . . . related to furnishing Medicaid." *Id.*

Second, the Intervening States' brief refers to the Wisconsin Medicaid Provider Agreement, which states: "Provider acknowledges that certain terms, conditions, and restrictions that are . . . set forth in applicable law . . . govern its participation as a provider in Wisconsin Medicaid, and that by submitting claims as a Wisconsin Medicaid Provider, the Provider becomes subject to those terms, conditions, and restrictions." Pl. Opp. at 11. Because the AKS is an "applicable law" that "govern[s]" Wisconsin Medicaid, the Provider Agreement constitutes an express certification of compliance with the AKS.

Third, the Intervening States' brief cites to Oklahoma Medicaid's Provider Agreements, which are required to include compliance certifications by statute. *See id.* at 10 n.4. The Oklahoma Administrative Code states:

> In order to be eligible for payment, providers must have on file with [Oklahoma Medicaid], an approved Provider Agreement. Through this agreement, the provider certifies all information submitted on claims is accurate and complete, assures that the State Agency's requirements are met and *assures compliance with all applicable Federal and State regulations*.

Okla. Admin. Code 317:30-3-2 (emphasis added). Given that the AKS is such an "applicable" federal law, the Oklahoma Medicaid Provider Agreement constitutes an express certification of compliance with the AKS.

In their brief, the Intervening States also reference three state statutes as bases for "implied" false certifications.[7] *See* Pl. Opp. at 10 n.4.

First, they cite a provision of the Indiana Administrative Code which provides: "Medicaid *reimbursement* is available for pharmacy services rendered by enrolled pharmacy providers, when such services are: (1) provided in accordance with *all applicable laws*, rules of the office, and Medicaid provider manual . . ." 405 Ind. Admin. Code § 5-24-1 (emphasis added). Because the AKS is such an "applicable" law, this statute "expressly" states that a pharmacy must comply with the AKS "in order to be *paid*" for claims submitted to Indiana Medicaid, *Mikes*, 274 F.3d at 700 (emphasis added); AKS compliance is not just a condition of participation in the program. Accordingly, this statute meets the *Mikes* requirements and provides a proper basis upon which to assert an implied certification of AKS compliance.

Second, the Intervening States cite a Maryland statute that sets forth the consequences for Medicaid providers that "fail[] to comply with applicable federal or State laws or regulations," including "Withholding of payment by the Program." Md. Code Regs. 10.09.03.09(A). This statute "expressly" conditions the payment of Medicaid claims on compliance with "applicable federal . . . laws" such as the AKS. Thus, this statute meets the *Mikes* requirement for implied certifications as well.

Third, the Intervening States cite a New Jersey statute that lists "items excluded from payment" under the state Medicaid program, including "Claims for services, goods or supplies which are furnished, rendered, prescribed or ordered *in violation of Federal or State civil or criminal statutes* . . ." N.J.A.C. 10:49-5.5(a)(17) (emphasis added). Because the AKS is such a "Federal . . . criminal statute," New Jersey law "expressly" conditions the payment of Medicaid

[7] The Intervening States cite no law in Illinois or Michigan that could provide a basis for an implied certification because the law "expressly" requires compliance with the AKS or a parallel state statute as a condition of reimbursement under Medicaid. *Mikes*, 274 F.3d at 700.

claims on compliance with the AKS. *Mikes*, 274 F.3d at 700. Thus, this statute also meets the requirements of *Mikes* as a basis for implied certifications.

As soon as the Multistate Complaint is amended to include references to these six states' "express" and "implied" certifications of AKS compliance as outlined in their brief, Georgia, Wisconsin, Oklahoma, Indiana, Maryland, and New Jersey will have adequately pled that claims submitted to their Medicaid programs were "false" for the entire time period in question. An amended complaint including those allegations must be filed within 10 business days of the date of this opinion.

However, neither the Multistate Complaint nor the Intervening States' brief points to any express or implied false certification that BioScrip made in connection with claims submitted to the Illinois or Michigan Medicaid program prior to March 2010. Unless the plaintiffs' amended complaint identifies compliance certifications that could have rendered claims submitted to those two programs "false," the Illinois and Michigan state FCA claims will be dismissed insofar as they relate to claims submitted before 2010.

B. Retroactivity

Novartis also challenges the Intervening States' claims under several of the state FCA statutes because those statutes were not enacted until after the beginning of the kickback schemes, which allegedly commenced in 2007. It argues that some of the state statutes are not retroactive, and it challenges the constitutionality of treating other state statutes as retroactive.

As I held in *Novartis V*, this aspect of Novartis's motion to dismiss is denied as premature. *See* Docket No. 233 at 56. Denial is without prejudice to renewal at trial.

III. The State Complaints Satisfy Rule 9(b).

Novartis moves to dismiss the State Complaints pursuant to Rule 9(b) for failure to plead fraud with adequate particularity.

To comply with Rule 9(b), a complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004). "In other words, Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud." *Polansky*, 2009 WL 1456582, at *4 (quoting *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997)).

Novartis contends that the Intervening States fail to plead their claims under the state analogues to the FCA because they do not plead the submission of false claims with the requisite particularity. As explained in *Novartis I*, the submission of a "claim" is an essential element of causes of action under FCA subsection (a)(1)(A) (presentation of a false claim) and subsection (a)(1)(B) (making a false statement material to a false claim), 31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B); the same is true for the parallel provisions of the state false claims statutes that are invoked by the Intervening States. Accordingly, the plaintiffs must plead that element with particularity. *See Novartis I*, 2014 WL 2324465, at *9.

A plaintiff satisfies Rule 9(b) by pleading the submission of false claims with a high enough degree of particularity that defendants can reasonably "identify particular false claims for payment that were submitted to the government." *Id.* at *12 (quoting *U.S. ex rel. Karvelas v. Melrose-Wakefield Hospital*, 360 F.3d 220, 232 (1st Cir. 2004)).

As discussed above, *see supra* at § II, the Intervening States contend that BioScrip's false certifications of compliance with the AKS and parallel state laws rendered all the Exjade claims that BioScrip submitted during the course of the five-year kickback scheme "false." For each

Intervening State, the State Complaints include the following identifying information about the false claims submitted to government programs: the name of the pharmacy billing the drug (BioScrip), the name of the drug billed (Exjade), the total number of claims submitted (which varies by state), the total reimbursement amount (which varies by state), the government program that reimbursed the claims (Medicaid), and the precise time period during which the claims were submitted (February 2007 to May 2012). *See* Multistate Compl. at ¶¶ 43-44; California Compl. at ¶¶ 29, 120; Washington Compl. at ¶¶ 52-53.

These allegations satisfy Rule 9(b), for the reasons stated in *Novartis I*. *See* 2014 WL 2324465, at *22-23.

Novartis also challenges the rest of the Intervening States' statutory and common law claims for failure to plead fraud with particularity. Novartis Br.[8] at 9. The heightened pleading standard of Rule 9(b) applies to state claims brought in federal court where those claims are premised on a defendant's underlying fraudulent conduct. *See O'Brien v. National Property Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991); *Silverman Partners, L.P. v. First Bank*, 687 F. Supp. 2d 269, 288 (E.D.N.Y. 2010). Novartis contends that the State Complaints do not describe the fraudulent scheme with sufficiency particularity to satisfy Rule 9(b). This argument fails for the reasons stated in *Novartis II*. *See* 2014 WL 2619014, at *4.

IV. Unjust Enrichment

Each of the Intervening States asserts a state common law claim for unjust enrichment. Generally, to prove such a claim, a plaintiff must show: (1) that the defendant was enriched, (2) at the plaintiff's expense, and (3) it would be inequitable for the defendant to retain the benefit. *See, e.g.*, *Phillips Int'l Inv. v. Pektor*, 117 A.D.3d 1, 4 (N.Y. 1st Dep't 2014). Unjust

[8] "Novartis Br." refers to Novartis's brief in support of its motion to dismiss the State Complaints.

enrichment is a quasi-contractual equitable claim that is sometimes referred to as a "restitution" or "quantum meruit" claim. *Newman & Schwartz v. Asplundh Tree Expert Co.*, 102 F.3d 660, 663 (2d Cir. 1996); *Seiden Associates, Inc. v. ANC Holdings, Inc.*, 768 F. Supp. 89, 96-97 (S.D.N.Y. 1991), *rev'd on other grounds*, 959 F.2d 425 (2d Cir. 1992). Properly stated, "restitution is the *remedy* for unjust enrichment, not a separate basis for liability." *State of N.Y. v. SCA Servs., Inc.*, 761 F. Supp. 14, 15 (S.D.N.Y. 1991) (emphasis added). Thus, "a plaintiff who establishes a prima facie case of unjust enrichment is entitled to the equitable remedy of restitution." *Id.*

Novartis challenges the sufficiency of several of the Intervening States' unjust enrichment claims.

First, Novartis argues that the laws of Indiana, Michigan, New York, Oklahoma, and Washington only permit plaintiffs to bring unjust enrichment claims where they have no adequate remedy at law. Novartis contends that the Intervening States do have adequate remedies at law for the challenged conduct—namely, their claims under state statutory and common law.

However, the Intervening States correctly point out that Rule 8 allows plaintiffs to plead in the alternative. It states: "A party may set out 2 or more statements of a claim or defense *alternatively* or hypothetically, either in a single count or defense or in separate ones. If a party makes alternative statements, the pleading is sufficient if any one of them is sufficient." FED. R. CIV. P. 8(d)(2) (emphasis added). Rule 8 also requires a plaintiff to include "demand for the relief sought" in his complaint, and provides that such relief "may include relief *in the alternative* or different types of relief." FED. R. CIV. P. 8(a)(3) (emphasis added). Accordingly,

the Intervening States contend that they may plead legal claims (such as their state FCA claims) while also pleading alternative equitable unjust enrichment claims in case their legal claims fail.

In FCA cases, courts permit government plaintiffs asserting FCA claims to plead unjust enrichment claims in the alternative; such claims are not properly dismissed at the pleading stage. *See U.S. ex rel. Heesch v. Diagnostic Physicians Grp., P.C.*, No. 11 Civ. 364, 2014 WL 2154241, at *11 n.2 (S.D. Ala. May 22, 2014); *U.S. v. Stevens*, 605 F. Supp. 2d 863, 869-70 (W.D. Ky. 2008); *U.S. ex rel. Miller v. Bill Harbert Intern. Const.*, 505 F. Supp. 2d 20, 24 (D.D.C. 2007); *U.S. v. Rogan*, 459 F. Supp. 2d 692, 721 (N.D. Ill. 2006), *aff'd*, 517 F.3d 449 (7th Cir. 2008); *U.S. ex rel. Taylor v. Gabelli*, No. 03 Civ 8762 (PAC), 2005 WL 2978921, at *13 (S.D.N.Y. Nov. 4, 2005); *Visiting Nurse Ass'n of Brooklyn v. Thompson*, 378 F. Supp. 2d 75, 99 (E.D.N.Y. 2004); *U.S. v. United Technologies Corp.*, 255 F. Supp. 2d 779, 785 (S.D. Ohio 2003); *U.S. ex rel. Purcell v. MWI Corp.*, 254 F. Supp. 2d 69, 79 (D.D.C. 2003); *U.S. v. Erie Cnty. Med. Ctr.*, No. 02 Civ 305E (SR), 2002 WL 31655004, at *1 (W.D.N.Y. Oct. 30, 2002). This Court will similarly allow the Intervening States' alternative unjust enrichment claims to proceed at this early stage of the case. Obviously, the plaintiffs cannot obtain a double recovery. And if a trier of fact concludes that a state cannot recover on a statutory false claims count because it failed to prove that the claims were in fact "false," unjust enrichment will not be available as an alternative remedy because it would not be "inequitable" for Novartis to retain the "benefit" it received from the Intervening States. *Pektor*, 117 A.D.3d at 4.

Second, Novartis contends that the laws of California, Georgia, and New Jersey do not recognize unjust enrichment as an independent cause of action in tort.

The Intervening States respond that these states are not raising unjust enrichment claims in tort, but rather as an "equitable remedy." Pl. Opp. at 21. Under Rule 8(a)(3), the Intervening

States may seek equitable relief "in the alternative;" thus, they may seek unjust enrichment (or "restitution") as an alternative to their remedies at law, such as damages. I deny the motion to dismiss at this stage in the case.

V. Washington's "Money Had and Received" Claim Is Duplicative of Its Unjust Enrichment Claim.

The Washington Complaint asserts a claim for "money had and received" (Count 6). Under Washington law, "an action for money had and received may be maintained against one who has money in his hands which he is not entitled to retain." *King County v. Odman, et al.*, 111 P.2d 228, 229-30 (Wash. 1941). Like unjust enrichment, "money had and received" is a quasi-contractual equitable claim; "the right of recovery arises independently of the express agreement or intent of the parties, where the facts are such that the holder of another's funds would be 'unjustly enriched' if the law did not presume a promise to pay." *Coast Trading Co. v. Parmac, Inc.*, 587 P.2d 1071, 1075 (Wash. Ct. App. 1978).

In *Davenport v. Washington Education Association*, 197 P.3d 686 (Wash. Ct. App. 2008), the Court of Appeals of Washington explained the history of "money had and received" actions:

> The action for money had and received was invented by the common-law judges to secure relief from the narrower restrictions of the common-law procedure, which afforded no remedy in too many cases of merit. The action is a modified form of assumpsit. It has gone through various transformations; first from tort, then from contract, and afterwards into a remedy where there was technically neither tort nor contract. It is founded on the principle that no one ought unjustly to enrich himself at the expense of another, and the gist of the action is that the defendant has received money which in equity and good conscience should have been paid to the plaintiff, and under such circumstances that he ought, by the ties of natural justice, to pay it over.

Id. at 697 (quoting *Bosworth v. Wolfe*, 146 Wash. 615, 623 (Wash. 1928)).

Novartis contends that Washington's "money had and received" claim is duplicative of its unjust enrichment claim. The Intervening States make little effort to rebut this argument.

Novartis is correct. Washington courts consider "money had and received" claims to be the equivalent of unjust enrichment claims. The *Davenport* court stated: "Sometimes termed a cause of action for 'a contract implied in law[,]' 'quasi contract,' or 'money had and received,' the common law action for restitution employs unjust enrichment as an independent basis of substantive liability." *Id.* at 697. Thus, a "money had and received" claim is just another name for a restitution or unjust enrichment claim. *See Coto Settlement v. Eisenberg*, 593 F.3d 1031, 1041 (9th Cir. 2010).

The State of Washington bases its "money had and received" claim on the same factual allegations as its unjust enrichment claim—that Novartis obtained Medicaid claim reimbursement money to which it is not equitably entitled. Accordingly, Washington's claim for "money had and received" (Count 6 of the Washington Complaint) is duplicative of its unjust enrichment claim and must be dismissed with prejudice.

VI. Washington Adequately Pleads Its Civil Conspiracy Claim.

The Washington Complaint also asserts a claim for "civil conspiracy" (Count 8). To establish a civil conspiracy under Washington law, a plaintiff must prove that (1) "two or more people combined to accomplish an unlawful purpose, or combined to accomplish a lawful purpose by unlawful means;" and (2) "the conspirators entered into an agreement to accomplish the conspiracy." *Webster v. Webster*, No. 40588-1-11, 2012 WL 628228, at *5 (Wash. Ct. App. Feb. 28, 2012). "Civil conspiracy is not, by itself, an actionable claim;" rather, the plaintiff "must be able to show an underlying actionable claim which was accomplished by the conspiracy for the civil claim of conspiracy to be valid." *Id.*

Novartis contends that Washington fails to adequately allege its civil conspiracy claim because the state fails to allege its other claims under state law; Novartis argues that the civil conspiracy claim "rises or falls with Washington's ability to plead some other common law claim." Novartis Reply[9] at 12-13. As several of Washington's statutory and common law claims remain (including its fraud claim), and Washington contends that the fraudulent scheme was accomplished by virtue of a conspiracy between Novartis and BioScrip, the civil conspiracy claim is adequately pled and the motion to dismiss is denied.

VII. Maryland Fails to Adequately Plead Its Negligent Misrepresentation Claim.

The Multistate Complaint asserts a claim for negligent misrepresentation under Maryland law. Negligent misrepresentation is a variant of negligence. In order to prove such a claim, a plaintiff must show that: (1) "the defendant, *owing a duty of care to the plaintiff*, negligently asserts a false statement;" (2) "the defendant intends that his statement will be acted upon by the plaintiff;" (3) "the defendant has knowledge that the plaintiff will probably rely on the statement, which, if erroneous, will cause loss or injury;" (4) "the plaintiff, justifiably, takes action in reliance on the statement;" and (5) "the plaintiff suffers damage proximately caused by the defendant's negligence." *Walpert, Smullian & Blumenthal, P.A. v. Katz*, 762 A.2d 582, 588 (Md. 2000) (emphasis added).

Novartis argues that the Intervening States have failed to allege the first element—that Novartis owed any duty to the State of Maryland.

Where a plaintiff alleges that a defendant's negligent misrepresentation caused him economic loss alone (as opposed to personal injury), Maryland courts find that the "duty"

[9] "Novartis Reply" refers to Novartis's reply brief in support of its motion to dismiss the State Complaints.

element of the claim is met only where there is an "intimate nexus" between the parties. *Id.* at 589. The intimate nexus test is satisfied by "contractual privity or its equivalent." *Id.*

Novartis owed no duty to the State of Maryland. As another district court has stated in the context of an FCA case, "There is no freestanding duty to provide accurate information to the Government." *U.S. ex rel. Mayman v. Martin Marietta Corp.*, 894 F. Supp. 218, 225 (D. Md. 1995). Further, there was no "intimate nexus" between the parties. *Katz*, 762 A.2d at 589. The Multistate Complaint alleges no contract between Novartis and the State of Maryland, and the parties had no other close relationship that could be considered the "equivalent" of contractual privity. *Id.*; *U.S. v. EER Sys. Corp.*, 950 F. Supp. 130, 133 (D. Md. 1996). According to the Multistate Complaint, Novartis did not even directly deal with the Maryland Medicaid program—BioScrip did.

Maryland's negligent misrepresentation claim (Count 22 in the Multistate Complaint) is dismissed with prejudice.

CONCLUSION

For the foregoing reasons, Novartis's motions to dismiss the State Complaints pursuant to Rules 12(b)(6) and 9(b) are granted in part and denied in part. They are granted with prejudice insofar as they concern Maryland's negligent misrepresentation claim (Count 22 of the Multistate Complaint) and Washington's "money had and received" claim (Count 6 of the Washington Complaint). The motions to dismiss are otherwise denied for the time being. I will dismiss the state FCA claims of Illinois and Michigan (Counts 5-8 and 25-28 of the Multistate Complaint) insofar as they relate to claims submitted to their state Medicaid programs prior to March 23, 2010, unless the Intervening States submit the information discussed above. *See supra* at § II.A.2.b.

The Clerk of the Court is directed to close out the motions at Docket Nos. 139 and 170 and to remove same from the Court's list of pending motions.

Dated: September 4, 2014

U.S.D.J.

BY ECF TO ALL COUNSEL